

NADA Number: 008-804

Trade Name	Terramycin® 100 Type A Medicated Article Terramycin® 50D Type A Medicated Article TM-100® Type A Medicated Article Terramycin® 10 Type A Medicated Articles Terramycin® Animal Mix TM-50® D Type A Medicated Article Terramycin® 100D Type A Medicated Article TM-100®D Type A Medicated Article Terramycin® 20 Type A Medicated Articles Terramycin® 100SS Type A Medicated Article Terramycin® 200 Type A Medicated Article Terramycin® 50 Type A Medicated Article TM-50® Type A Medicated Article
Sponsor	Phibro Animal Health
Ingredients	Oxytetracycline Hydrochloride
Species	BEES (Honey bees) CATTLE (Cattle, dairy, not lactating) CATTLE (Cattle, calves) CATTLE (Cattle, beef) CHICKENS (Chicken, not laying eggs for human consumption) CRUSTACEANS (Lobster) FISH (Pacific salmon, reared) FISH (Salmonids, reared) FISH (Catfish, reared) SHEEP (DOMESTIC) (Sheep, no use class stated or implied) SWINE (Swine, no use class stated or implied) SWINE (Swine, breeding swine) TURKEYS (Turkey, not laying eggs for human consumption) TURKEYS (Turkey, growing)
Routes of Administration	Per Os
Dosage Form	Medicated feed
Dispensing Status	OTC
Dosage Amount, Indications & Limitations	558.450 Oxytetracycline. Specifications: Type A medicated articles containing 10, 20, 30, 50, 100 and 200 grams per pound. Conditions of use: Chickens Amount: 10 - 50 grams per ton of feed. Indications: For increased rate of weight gain and improved feed efficiency in broiler/fryer chickens. Limitations: Do not feed to chickens producing eggs for human consumption. Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS." Amount: 100 - 200 grams per ton of feed. Indications: Control of infectious synovitis caused by Mycoplasma synoviae; control of fowl cholera caused by Pasteurella multocida susceptible to oxytetracycline. Limitations: Feed continuously for 7 to 14 days. Do not feed to chickens producing eggs for human consumption. In low calcium feed withdraw 3 days before slaughter. Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS." Amount: 400 grams per ton of feed. Indications: For control of chronic respiratory disease (CRD) and air sac infection caused by M. gallisepticum and Escherichia coli susceptible to oxytetracycline. Limitations: Feed continuously for 7 to 14 days. Do not feed to chickens producing eggs for human consumption. In low calcium feed withdraw 3 days before slaughter. Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS." Amount: 500 grams per ton of feed. Indications: For reduction of mortality due to air sacculitis (air-sac infection) caused by E. coli susceptible to oxytetracycline. Limitations: Feed continuously for 5 days. Do not feed to chickens producing eggs for human consumption. In low calcium feed withdraw 3 days before slaughter. Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS." Turkeys (growing) Amount: 10 - 50 grams per ton of feed.

Indications: For an increased rate of weight gain and improved feed efficiency.

Limitations: Do not feed to turkeys producing eggs for human consumption. Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Amount: 100 grams per ton of feed.

Indications: For control of hexamitiasis caused by *Hexamita meleagridis* susceptible to oxytetracycline.

Limitations: Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption. Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Amount: 200 grams per ton of feed.

Indications: For control of infectious synovitis caused by *M. synoviae* susceptible to oxytetracycline.

Limitations: Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption. Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Amount: 25 milligrams per pound of body weight.

Indications: For control of complicating bacterial organisms associated with bluecomb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline.

Limitations: Feed continuously for 7 to 14 days. Do not feed to turkeys producing eggs for human consumption. Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Swine

Amount: 10 - 50 grams per ton of feed.

Indications: For an increased rate of weight gain and improved feed efficiency.

Limitations: Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Amount: 10 milligrams per pound of body weight.

Indications: For treatment of bacterial enteritis caused by *E. coli* and *Salmonella choleraesuis* susceptible to oxytetracycline and treatment of bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline.

Limitations: Feed continuously for 7 to 14 days. Withdraw 0 days before slaughter. Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Swine (breeding)

Amount: 10 milligrams per pound of body weight.

Indications: For control and treatment of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by *Leptospira pomona* susceptible to oxytetracycline. Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Limitations: Feed continuously for not more than 14 days. Withdraw 0 days before slaughter.

Cattle (calves up to 250 pounds)

Amount: 0.05 - 0.1 milligrams per pound of body weight.

Indications: For an increased rate of weight gain and improved feed efficiency.

Limitations: Feed continuously. In milk replacers or starter feed. Withdraw 0 days before slaughter. Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Cattle (calves and beef and non-lactating dairy)

Amount: 10 milligrams per pound of body weight daily.

Indications: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia (shipping fever complex) caused by *P. multocida* susceptible to oxytetracycline.

Limitations: Feed continuously for 7 to 14 days. In feed or milk replacers. Withdraw 0 days before slaughter. Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Cattle (calves up to 250 pounds)

Amount: 10 milligrams per pound of body weight daily.

Indications: For treatment of bacterial enteritis caused by *E. coli* susceptible to oxytetracycline.

Limitations: Feed continuously for 7 to 14 days. In milk replacers or starter feed. Withdraw 0 days before slaughter. Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Cattle (calves 250 to 400 pounds)

Amount: 25 milligrams per head per day. Indications: For increased rate of weight gain and improved feed efficiency.

Limitations: Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Cattle (growing cattle over 400 pounds)

Amount: 75 milligrams per head per day.

Indications: For increased rate of weight gain, improved feed efficiency, and reduction of condemnation due to liver abscesses.

Limitations: Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Cattle

Amount: 0.5 - 2.0 grams per head per day in feed.

Indications: For prevention and treatment of the early stages of shipping fever complex.

Limitations: Feed 3 to 5 days before and after arrival in feedlots. Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Sheep

Amount: 10 - 20 grams per ton of feed.

Indications: For increase rate of weight gain and improved feed efficiency.

Limitations: Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Amount: 10 milligrams per pound of body weight daily.

Indications: For treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to oxytetracycline.

Limitations: Feed continuously for 7 to 14 days. Withdraw 5 days before slaughter. Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Honey bees

Amount: 200 milligrams per colony.

Indications: For control of American foulbrood caused by *Bacillus larvae* and European foulbrood caused by *Streptococcus pluton* susceptible to oxytetracycline.

Limitations: Remove at least 6 weeks prior to main honey flow. Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Lobsters

Amount: 1 gram per pound medicated feed.

Indications: For control of gaffkemia caused by *Aerococcus viridans*.

Limitations: Administer as sole ration for 5 days in feed. Withdraw medicated feed at least 30 days before harvesting. Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Pacific salmon

Amount: 250 milligrams per kilogram of fish per day.

Indications: For marking of skeletal tissue.

Limitations: For salmon not over 30 grams body weight. Administer as sole ration for 4 consecutive days. Not to be liberated for at least 7 days following the last administration of medicated feed. Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Salmonids

Amount: 2.5 to 3.75 grams per 100 pounds of fish per day.

Indications: For control of ulcer disease caused by *Hemophilus piscium*, furunculosis caused by *Aeromonas salmonicida*, bacterial hemorrhagic septicemia caused by *A. liquefaciens*, and pseudomonas disease.

Limitations: Administer in mixed ration for 10 days. Do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed. Do not administer when water temperature is below 9 degrees C (48.2 degrees F). Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."

Catfish

Amount: 2.5 - 3.75 grams per 100 pounds of fish per day.

	<p>Indications: For control of bacterial hemorrhagic septicemia caused by <i>A. liquefaciens</i> and <i>pseudomonas</i> disease.</p> <p>Limitations: Administer in mixed ration for 10 days. Do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed. Do not administer when water temperature is below 16.7 degrees C (62 degrees F). Labeling shall bear the statement "FOR USE IN DRY ANIMAL FEED ONLY. NOT FOR USE IN LIQUID FEED SUPPLEMENTS."</p>
Tolerances	<p>Oxytetracycline Hydrochloride: Beef cattle, dairy cattle, calves, swine, sheep, chickens, turkeys, finfish and lobster. Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues and milk as follows: a. 2 parts per million (ppm) in muscle b. 6 ppm in liver c. 12 ppm in fat and kidney d. 0.3 ppm in milk.</p>